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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,722	04/16/2001	Mike Farwick	P 280112 000551 BT	3966

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PILLSBURY WINTHROP, LLP  
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EXAMINER
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FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/02/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/834,722

Applicant(s)

FARWICK ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 20, 23, 30 and 33-36 is/are allowed.
- 6) ☐ Claim(s) 21, 22, 24-29, 31, and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

1. Claims 20-36 are under consideration in this Office Action.

#### *Claim Objections*

2. Claims 21 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 20. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21, 22, 24, 25, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or an isolated polynucleotide comprising SEQ ID NO: 1; does not reasonably provide enablement for any other embodiment.

Applicants' arguments filed 7/11/2003 (Paper No.21) have been fully considered but they are not persuasive for reasons of record and for the following reasons listed below. Applicants' position is that the claimed invention is enabled by the specification since the specification teaches how to identify and search for the claimed polynucleotides.

The nature and breadth of the claims encompass any polynucleotide that is at least 90% or 95% identical to a polynucleotide encoding a polypeptide that has the amino acid sequence of SEQ ID NO: 2 or polynucleotide of SEQ ID NO: 1. While the specification teaches how to search and identify the claimed polynucleotides, the specification does not teach how to make the claimed polynucleotides. Guidance on how to search and screen for said polynucleotides is not guidance for making said polynucleotides. However, the specification does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function

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which cannot be altered.

The amount of experimentation to make the claimed polynucleotide is enormous, undue, and entails selecting specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make the claimed polynucleotides and determining by assays whether the polypeptide has activity. The specification does not provide guidance with respect to the specific structural/catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make the claimed polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue.

5. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention encompass any vector that is an integration vector pCR.1menEint of any nucleotide sequence having an internal 520bp fragment of any menE gene of any nucleotide sequence. The specification, however, only teaches a vector deposited in E.coli strain Top10/pCR2.1 menEint under accession no. DSM 14080. The specification does not provide a written description of any vector that is an integration vector pCR.1menEint of any nucleotide sequence having an internal 520bp fragment of any menE gene of any nucleotide sequence.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claims 31 and 32 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors

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are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The claims encompass any nucleic acid of any nucleotide sequence consisting of at least 40 consecutive nucleotides of SEQ ID NO: 1, wherein the nucleic acid functions as a primer or probe. The state of the prior art as exemplified by Wallace et al and Sambrook et al is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable (Sambrook et al. 'Types and uses of oligonucleotide probes'. In: Molecular Cloning A laboratory manual, 1989 second edition, pp. 11.3-11.10; Wallace et al. Oligonucleotide Probes for the screening of recombinant DNA libraries. Methods Enzymol. 1987, Vol. 152, pp.432-443). Even if the probe is a 20mer, the total number of hits in a database search was 143,797,728 which suggest that some of the probes encompassed by the claims would not preferentially hybridize to SEQ ID NO: 1. Therefore, predictability of which oligonucleotides or probes hybridize specifically to SEQ ID NO: 1 would require undue experimentation of one skilled in the art to practice the claimed invention.

#### ***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the phrase "identical to the extent of at least 70% to a polynucleotide which codes for a polypeptide which comprises the amino acid sequence of" SEQ ID NO: 2" is vague and indefinite because the specific nucleotide sequence to which the claimed polynucleotide has 70% identity to is not known and not defined in the specification. Furthermore, the phrase "the polypeptide preferably having the activity of O-succinylbenzoic acid CoA ligase" renders the claim vague and indefinite because it is not known if the claimed polypeptide has the recited activity.

#### ***Conclusion***

9. Claims 20, 23, 30, and 33-36 are allowed.


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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



Christian L. Fronda  
Examiner  
Patent and Trademark Office  
U.S. Department of Commerce